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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/761,424 | 01/22/2004 | William J. Carroll | 000309-00053 | 1421 |
| 27557 | 7590 | 09/09/2005 | EXAMINER | |
| BLANK ROME LLP 600 NEW HAMPSHIRE AVENUE, N.W. WASHINGTON, DC 20037 | | | FAULCON JR, LENWOOD | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3762 | |

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---|---------------------------------------|--|
| Office Action Summary | Application No. 10/761,424 | Applicant(s) CARROLL ET AL. | |
| | Examiner Lenwood Faulcon, Jr. | Art Unit 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/20/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Thomas (U.S. Patent No. 5,107,835).

Thomas teaches of an apparatus and method for reliving symptoms associated with injured tissue (col. 2 lines 13-15), such as pain (col. 12 lines 11-19), by electrical stimulation. Thomas further teaches of a sine-wave interferential current generator (col. 2 lines 18-32) with a frequency of 10kHz (col. 3 lines 21-23). Thomas also teaches of the apparatus and method utilizing two pair of pads (electrodes), which can be in the form of an internal applicator (col. 5 lines 34-45).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2-3, 8-10, 12-13, 16-17, 22-24, 26-27, 29-31, 36-39 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas as applied to claims 1 above, and further in view of Madsen et al. (U.S. Patent No. 5,776,173).

Madsen et al. teaches of a portable interferential electro-stimulation device (col. 4 lines 15-19), which uses generated digital signals (col. 7 lines 24-26) and a programmable digital signal processor (col. 3 lines 31-34). Madsen et al. further teaches that the stimulator supports quadrapolar therapy (col. 4 lines 19-23).

It would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Thomas as applied above with the teachings of Madsen et al. to have a method and apparatus for electrical stimulation that utilizes generated digital signals along with a digital signal processor or a field-programmable gate array. Thomas and Madsen et al. both teach of interferential stimulation devices that treat pain, and thus teach of analogous arts. It would have been have obvious to one having ordinary skill in the art at the time of the invention to modify the device and method as taught by Thomas to utilize generated digital signals, digital signal processors to enhance the effectiveness of the treatment. It would have also been obvious to one having ordinary skill in the art at the time of the invention to modify the device as taught by Madsen et al. to include a field-programmable gate array and quadripolar leads to provide the appropriate therapy a patient needs, as suggested by Madsen et al. (col. 5 lines 5-7, col. 4 lines 19-23). Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Thomas and Madsen et al. to have the limitations of claims 2-3, 8-10, 12-13, 16-17, 22-24, 26-27, 29-31, 36-39 and 42.

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas (U.S. Patent No. 5,107,835) as applied to claims 1 and 15 above, and further in view of Matthews (U.S. Patent No. 5,269,304).

Matthews teaches of an electro-therapy apparatus for relieving pain (col. 1 lines 5-9), that uses two feed electrodes that supply current at different frequencies to provide a resultant therapeutic beat frequency does not exceed 250 Hz (col. 2 lines 14-19).

It would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Thomas as applied above with the teachings of Matthews to have interferential stimulation device that produces a therapeutic beat frequency that does not exceed 250 Hz. Thomas and Matthews both teach of interferential stimulation devices that treat pain, and thus teach of analogous arts. It would have been obvious to one having ordinary skill in the art to modify the device and method taught by Thomas to produce a therapeutic beat frequency that does not exceed 250 Hz, since it is well know that such frequencies are well known for treating pain, as taught by Matthews (col. 1 lines 12-14). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Thomas and Matthews to have the limitations of claim 4.

6. Claims 5-7 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas (U.S. Patent No. 5,107,835) as applied to claims 1 and 15 above, and further in view of Terry et al. (U.S. Patent No. 5,215,086).

Terry et al. teaches of a method and device for therapeutic treatment of migraine symptoms by stimulation, in which the current includes a voltage output with a

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maximum of 14 volts (col. 12 lines 9-12) and pulse widths that can have various ranges depending on the patient's needs (col. 2 lines 25-33).

It would have been obvious to one having ordinary skill in the art at the of the invention to combine the teachings of Thomas as applied above with the teachings of Terry et al. to have an interferential stimulation device that has a maximum output of 11 volts and a pulse width of 210 microseconds. Thomas and Terry et al. both teach of therapeutic stimulation devices for treating pain, and thus teach of analogous arts. It would obvious to one having ordinary skill in the art to modify the device and method as taught by Thomas to have a maximum output of 11 volts for each circuit to prevent injury to the patient, as taught by Terry et al. (col. 12 lines 12-13). It would have also been obvious to one having ordinary skill in the art to modify the device and method as taught by Thomas to have a pulse width of 210 microseconds and provide a range of at least 10-600 microseconds, as deemed necessary to treat the patient's particular needs, as taught by Terry et al. (col. 4 lines 28-53). Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Thomas with the teachings of Terry et al. to have the limitations of claims 5-7 and 19-21.

7. Claims 11, 14, 18, 25, 28, 32 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas (U.S. Patent No. 5,107,835) in view of Madsen et al. ((U.S. Patent No. 5,776,173) as applied to claims above, and further in view of Matthews (U.S. Patent No. 5,269,304) as applied to claim 4 above.

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It would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Thomas and Madsen et al. as applied to claims 2-3, 8-10, 12-13, 16-17, 22-24, 26-27, 29-31, 36-39 and 42 above, with the teachings of Matthews as applied to claim 4 above, to have interferential stimulation device that produces a therapeutic beat frequency that does not exceed 250 Hz. Thomas, Madsen et al. and Matthews all teach of interferential stimulation devices that treat pain, and thus they teach of analogous arts. It would have been obvious to one having ordinary skill in the art to modify the devices and methods taught by Thomas and Madsen et al. to produce a therapeutic beat frequency that does not exceed 250 Hz, since it is well know that such frequencies are well known for treating pain, as taught by Matthews (col. 1 lines 12-14). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Thomas, Madsen et al. and Matthews to have the limitations of claims 11, 14, 18, 25, 28, 32 and 40.

8. Claims 33-35 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas (U.S. Patent No. 5,107,835) in view of Madsen et al. ((U.S. Patent No. 5,776,173) as applied to claims 2-3, 8-10, 12-13, 16-17, 22-24, 26-27, 29-31, 36-39 and 42 above, and further in view of Terry et al. (U.S. Patent No. 5,215,086) as applied to claims 5-7 and 19-21.

It would have been obvious to one having ordinary skill in the art at the of the invention to combine the teachings of Thomas and Madsen et al. as applied above with the teachings of Terry et al. as applied above to have an interferential stimulation device

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that has a maximum output of 11 volts and a pulse width of 210 microseconds.

Thomas, Madsen et al. and Terry et al. all teach of therapeutic stimulation devices for treating pain, and thus they teach of analogous arts. It would obvious to one having ordinary skill in the art to modify the device and method as taught by Thomas to have a maximum output of 11 volts for each circuit to prevent injury to the patient, as taught by Terry et al. (col. 12 lines 12-13). It would have also been obvious to one having ordinary skill in the art to modify the device and method as taught by Thomas to have a pulse width of 210 microseconds and provide a range of at least 10-600 microseconds, as deemed necessary to treat the patient's particular needs, as taught by Terry et al. (col. 4 lines 28-53). Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Thomas, Madsen et al. and Terry et al. to have the limitations of claims 33-35 and 41.

Response to Arguments

9. Applicant's arguments filed June 20, 2005 have been fully considered but they are not persuasive. Thomas teaches that is well known in the art to have electrical stimulation by an interference type apparatus, in which the interference apparatus operates by applying to primary signals of relatively high but slightly different frequencies to a patient's body (col. 1 lines 10-19). It is inherent in the system as taught by Thomas that the electrode pairs create separate electrical circuits and have the ability to transmit sine waves of different frequencies (col. 2 lines 18-32). Thomas further teaches of a sum signal being applied by an internal applicator that is inserted into the body of the patient (col. 5 lines 41-45), which is interpreted to include

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applications such as implantable electrodes. Therefore, Thomas anticipates claims 1 and 15, is obvious over claims 2-3, 8-10, 12-13, 16-17, 22-24, 26-27, 29-31, 36-39 and 42 in view of Madsen et al., is obvious over claim 4 in view of Matthews, is obvious over claims 5-7 and 19-21 in view of Terry et al., is obvious over claims 11, 14, 18, 25, 28, 32 and 40 in view of Madsen et al. and further in view of Matthews, and it would have been obvious over claims 33-35 and 41 in view of Madsen et al. and further in view of Terry et al.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Griffith (U.S. Patent No. 3,096,768), Zilber (U.S. Patent No. 3,822,708), Nemec (U.S. Patent No. 4,153,061), Hudek et al. (U.S. Patent No. 4,374,524), Garcia-Rill et al. (U.S. Patent No. 5,002,053), Gamble (U.S. Patent No. 5,161,530), Hrdlicka et al. (U.S. Patent No. 5,443,486), Mann (U.S. Patent No. 6,052,624).

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lenwood Faulcon, Jr. whose telephone number is 571-272-6090. The examiner can normally be reached on Monday-Thursday from 9 to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes, can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lenwood Faulcon, Jr.



George Manuel

Primary Examiner